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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,562	01/07/2005	Karin Golz-Berner	3975.039	5263
36448 7550 AKERMAN SENTERFTIT P.O. BOX 3188 WEST PALM BEACH, FL 33402-3188			EXAMINER	
			CHUI, MEI PING	
			ART UNIT	PAPER NUMBER
			NOTIFICATION DATE	DELIVERY MODE
			08/19/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Application No. Applicant(s) 10/520,562 GOLZ-BERNER ET AL. Office Action Summary Examiner Art Unit MEI-PING CHUI 1616 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 27 April 2010. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-5 and 7 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 1-5 and 7 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.

1) Notice of References Cited (PTO-892)

Paper No(s)/Mail Date 04/27/2010.

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(c) (FTO/SB/CS)

Attachment(s)

Interview Summary (PTO-413)
 Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Application.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 04/27/2010 has been entered.

Status of Action

Accordingly, claims 1-5 and 7 are pending in the application and claim 6 has been previously cancelled in this application.

Receipt of Information Disclosure Statement filed on 04/27/2010 is acknowledged. It has been considered and placed in the file.

The indicated allowability of claims 1-5 and 7 is withdrawn in view of the newly discovered references to JP-11060496, JP11263718 and JP-61289010. Rejections based on the newly cited references follow.

Status of Claims

Accordingly, claims 1-5 and 7 are presented for examination on the merits for patentability.

Art Unit: 1616

Claim Rejections - 35 USC § 112 second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-5 and 7 are rejected 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. All dependent claims are also included in this rejection.

Claims 1, 5 and 7 recite the constituents "a plankton extract containing the photolyase enzyme" (see: claims 1, line 6; claim 5, line 7; claim 7, line 8); "a micrococcus lysate containing the UV-endonuclease enzyme" (claims 1, line 9; claim 5, line 10; claim 7, line 11); "a product obtained by extracting the bark of Quebracho blanco" and "a silkworm extract obtained by extraction, which extract contains the eccropine peptide" (see claim 5, line 23 and line 28), in which the recitation of "the photolyase enzyme", "the UV-endonuclease enzyme", "the bark of Quebracho blanco" and "the eccropine peptide" lack sufficient antecedent basis because these constituents are not recited in the precedent body of the claims.

Claim Rejections - 35 USC § 103

35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

⁽a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- Resolving the level of ordinary skill in the pertinent art.
- Considering objective evidence present in the application indicating obviousness or nonohylousness

Claims 1-5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Golz-Berner et al. (CA 2335149) and Burmeister et al. (EP 0707844 A2) combined, and in view of Murad, H. (WO 00/64472), Soma et al. (JP-11060496), Fujimura et al. (JP-11-263718) and Hiroaki et al. (JP-61289010 A) combined.

Applicants Claim

Applicants claim an anti-ageing skin cosmetic composition, and a method of reducing wrinkles and for prolonging the period for a visibly wrinkle-free skin, comprising a mixture of:

(a) an extract from fig leaves and fruits; (b) an extract from pomegranate fruits; (c) a ground dry mixture of rosemary stems and leaves; (d) an extract from peeled musk melons; (e) liposomes containing a planktons extract; and (f) liposomes containing a micrococcus lysate; wherein the cosmetic composition also comprises (g) an active formulation containing an extract from bark of Quebracho blanco; an extract from silkworm; hydrogel; phospholipids; additives, i.e. silicone wax, preservative, Na-EDTA, butylene glycols, carbomer, hydroxyethyl cellulose, triethanolamine, xanthan gum, glycerine, ethanol, PEG-40, benzophenone-4; water, and optional common ingredients, i.e. perfume, colorant, other active substances, carriers, adjuvants.

Art Unit: 1616

Determination of the scope and content of the prior art (MPEP 2141.01)

Golz-Berner et al. teach a cosmetic composition comprising active substances that has a particularly high radical protection potential and can be kept for a long period of time (page 2, lines 15-20). Golz-Berner et al. teach that the active substances have a high radical protection factor, wherein the actives substances include a product obtained by extracting bark of Quebracho blanco and subsequent enzymatic hydrolysis, which product contains at least 90% by weight proanthocyanidine oligomers and up to 10% by weight gallic acid, wherein the content of the active substance (a) has a concentration of 2% by weight linked to a microcapsules, ranging from 0.1 and 10% by weight; (b) a silkworm extract obtained by extraction, which extract contains eccropine peptide, amino acids and a vitamin mixture, wherein the content of (b) ranging between 0.1 and 10% by weight; (c) a non-ionic, cationic or anionic hydro-gel or hydrogel mixture, wherein the content of (c) ranging between 0.1 and 5% by weight (page 2, lines 29 through page 3, line 11).

Golz-Berner et al. also teach that the components (a) and (b) of the active substance in the composition and the phospholipids (d) presumably form association-like configurations of different molecules which again are accumulated mostly homogeneously in the generating structure of the gel (c) and (e), the whole being called "association complex" (see page 5, lines 29-36):

Golz-Berner et al. further teach that the composition also comprises a mixture of liposomal Micrococcus luteus extract prepared with phospholipids in 0.1 % by weight and phospholipids, which is presented in 0.2 % to 5 % by weight. Golz-Berner et al. teach that the

phospholipids contain phosphatidyl choline, phosphatidyl ethanolamine (page 5, lines 22-24). Golz-Berner et al. teach then that water as the remaining portion up to 100 % by weight along with other auxiliary or carrier substances (page 3, lines 21-25 and page 3-5).

Furthermore, Golz-Berner et al. teach the cosmetic composition also comprises additional components, i.e. plant extracts such as citric peel, fruit or leaves extract, which can present in 0.5 % to 20 % by weight; fruit extract, which can present up to 20 % by weight; plankton extract obtained from algae, which can bind to free radicals or moisture and can be present in an amount from 0.5 % to 20 % by weight; alcohols; hydrogels (e.g. hydroxyethyl cellulose); waxes, carbomer; the encapsulated mixture of 0.1 % by weight of *Micrococcus luteus* extract; UV filters, i.e. benzophenone derivatives, emulsifiers, i.e. glycerin, polyglucosides such as cellulose. More specifically, Golz-Berner et al. teach carbomer present in 0.2 %, glycerin present in 2.0 %, triethanolamine present in 0.2 %, perfume present in 0.5 %, preserving agent present in 0.3 %, by weight, and water adjusted to 100 % by weight (entire page 5-6; page 8, lines 34-36; page 10, lines 13-32 and page 12, lines 1-3; page 16-18: examples 1-4).

Burmeister et al. teach exposure to UV light from natural sunlight or from artificial sources has both beneficial and harmful effects upon the skin and general health of exposed individuals, where harmful effects of UV exposure range from mild to potential life threatening. Over-exposure to UV radiation can lead to premature aging of the skin and external characteristics of this condition include dry, wrinkled, thin skin with diminished elasticity. This loss in elasticity is associated at the cell and tissue level with decreases in collagen (page 2: lines 9-24, 40-45).

Art Unit: 1616

In order to rejuvenate and repair UV-damaged skin, Burmeister et al. teach a method for topical application of an effective amount of a composition to human skin, wherein the composition comprises a liposomal delivery system for delivering two or more active ingredients into the living dermis utilizing one or more DNA repair enzymes to enhance the delivery of active ingredients into the dermis (page 3: lines 18-33; page 4: lines 22-24, 37-42).

Burmeister et al. also teach that the one or more DNA repair enzymes are of the type which can repair UV-damaged DNA, and the preferred DNA repair enzyme is a photolyase that is present in a cell extract from *Micrococcus leuteus*. Other suitable enzymes include UV-DNA endonucleases can also be employed (page 4: lines 22-24; page 7, line 52 to page 8, line 4; page 13, claims 18-19).

Burmeister et al. also teach that the liposomes used in the system are primarily water and phospholipidcholine esters of phosphoric acid and a mixture of fatty acid digylcerides, i.e. plant-derived lecithin which is found in all living organisms and is a naturally occurring phospholipid having excellent color and odor stability; thus it is suitable for use in cosmetic products (page 2: lines 52-58; page 4, line 56 to page 5: line 7).

Burmeister et al. then teach that the concentration of phospholipids in the composition ranges from about 1 % to about 2 % by weight (page 5, lines 8-9; page 10-11, see Ultrasome™ in Examples 3 & 4).

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

Golz-Berner et al. and Burmeister et al. combine do not teach the constituents: an extract from a mixture of fig leaves and fruits (0.1-5 % by weight), an extract from pomegranate fruits

Art Unit: 1616

(0.1-3 % by weight), a ground dry mixture of rosemary stems and leaves (0.001-0.5 % by weight); an extract from peeled musk melons (0.01-3 % by weight), as claimed. However, the deficiencies are cured by Murad, H., Soma et al. and Fujimura et al. combined.

Murad, H. teaches a method and a composition for treating dermatological conditions, i.e. skin wrinkle or UV damage caused by exposure to UV light. Murad, H. teaches that the composition comprises one or more fruit extracts containing antioxidants, i.e. pomegranate, in an amount sufficient to neutralize free radicals and pharmaceutical acceptable carriers (page 8, lines 27-30), wherein the composition also comprises additional extracts, i.e. rosemary extract, to facilitate managing the dermatological conditions. Murad, H. teaches that the fruit extracts can be presented in an amount from about 0.01 % to 80 % by weight, preferably 0.5 % to 10 % by weight. In addition, Murad, H. teach that any fruit extracts capable of preventing, treating or managing skin disorders and/or skin damage is suitable for use in the composition and the method (page 9, line 14 and page 11, lines 14-25).

More specifically, Murad, H. teaches a skin treatment composition comprises water (about 18-95 % by weight) and additives, i.e. hydroxyethyl cellulose (0.1-2.0 % by weight); EDTA (0.01 % to 1.0 % by weight); butylene glycol (0.5-7 % by weight); denatured alcohol (0.01-15 % by weight); pomegranate extract (0.01-3.0 % by weight); fragrance or perfume (0.01-1.0 % by weight) (page 29-31: Example 5); triethanolamine (0.5-1.0 % by weight) (page 42: Example 11); benzophenone-4 (0.01-5 % by weight) (page 36: Example 8); acceptable carriers.

Soma et al. teach an agent for enhancing hyaluronic acid productivity in a tissue or cell
of a mammal, characterized in that the agent for enhancing hyaluronic acid productivity contains
an extract of at least one plant belonging to the family Moraceae in an amount sufficient to

Art Unit: 1616

enhance the production of the hyaluronic acid, wherein the family Moraceae plants belonging to the genus Ficus includes the fruits and leaf of *Ficus carica* (page 2, claims 1-3; page 7: [0011]). Soma et al. also teach that the tissue or cell of a mammal is a human epidermal cell or tissue containing said cell (page 3, claim 5).

More specifically, Soma et al. teach that hyaluronic acid is widely distributed in vivo, in skin, it plays an important role in skin with regards to cell adhesion, protection of cells, formation of skin tissue, tissue moisture maintenance, and maintenance of flexibility. Phenomena that occur as symptoms of aging skin include "lowering of wetness" and "lowering of tenseness," which are accompanied by "wrinkles" and "sagging" for example. The causes of these phenomena have not yet been completely clarified, but it is thought that one factor is the decrease in production of hyaluronic acid by skin cells that accompanies aging, and the decrease in skin moisture content influences skin function (page 4: [0003]). Thus, it is desirable to offer a substance that is high in safety, that acts directly on skin cells, and that promotes production of hyaluronic acid by skin tissue more strongly. Accordingly, the object of the present invention is to provide a substance that is superior to conventional plant extracts in activity to enhancement of hyaluronic acid productivity, and that exhibit the aforementioned enhancement activity cells and tissue other than the skin (page 5: [0004]).

Soma et al. then teach that the amount that is to be blended of plant extract for the agent for enhancing hyaluronic acid productivity is an amount that is sufficient to enable enhancement of hyaluronic acid productivity in mammalian tissue or cells, and particularly in human skin cells because an optimal amount varies according to factors such as the age of the person using it and

Art Unit: 1616

individual differences, but generally 0.0001 to 20% by weight, preferably 0.005 to 5% by weight is suitable when applied to skin (page 8: [0013]).

Furthermore, Soma et al. teach that other than the plant extract, i.e. the extract from the fruits and leaf of *Ficus carica*, additional ingredients that are for external application can also be included for enhancing hyaluronic acid productivity within a range does not adversely influence efficacy of the active ingredients contained in the extract, wherein said additives ingredients commonly used in external preparations include carriers, diluents, auxiliaries and other active compounds used alone or in combination. Examples for those additives, such as surfactants (i.e. waxes such as silicone oils), humectants, thickeners, preservatives, chelating agents, pH adjusting agents, fragrances, colorants, UV-absorbers (page 8-10: [0014-0016]).

Fujimura et al. teach that the dermal layer of the skin is extremely important for maintaining the structure of the skin. It is composed of rigid and soft fibers including collagen, fibronectin, and elastin that form the connective tissue for the dermis, and the interaction between the skin fibroblasts and the extracellular matrix, such as collagen, is deeply related to preserving or losing skin tightness. However, when the skin is constantly being exposed to external irritations by drying, UV rays, and such, and along with aging, tightness and elasticity are lost, and sagging occurs (page 3: [0004], [0006]).

Fujimura et al. teach that one way to solve the problems of sagging and lost of skin elasticity, an agent that can ameliorate sagging and tightening of skin would be useful. Fujimura et al. then teach that rosemary plants (or extracts) are well known as external skin preparations, cosmetics, raw materials for medicinal products, base materials, and additives. Moreover, it is

Art Unit: 1616

also known that they have effects, such as humidifying effects, anti-inflammatory, blood circulation promoting, hair tonic, and skin beautifying effects (page 3: [0004]; page 5: [0012]).

Fujimura et al. teach an agent for ameliorating sagging and tightening of skin comprising an integrin expression promoting agent for human skin cells as an active ingredient, wherein the human skin cells are human skin fibroblasts and the integrin expression promoting substance is plants of rosemary, and wherein the plants use in the agent can be one or more of their leaves, leaf stalks, stems, roots, and seeds, or the dried and crushed products thereof (page 2, claims 1, 3-4; page 6: [0013]).

Fujimura et al. also teach that the content of the plants, i.e. rosemary, in the agent for ameliorating sagging of the skin and tightening of the skin normally is preferably 0.00001 to 10 % by weight, and in particular preferably 0.0001 to 3% by weight as a dried solid content of the effective ingredient, from the viewpoints of the effects, the compoundability, and the feeling in use (page 7: [0017]). Additional ingredients, such as silicone oil, natural glyceride, humectants, UV-absorbers, alcohols, chelating agents, pH modifiers, preservatives, thickeners, colorants, fragrances can be included in the agent (page 8: [0018]).

Hiroaki et al. teach a cosmetic composition comprising an extract of cucurbitaceous plant, i.e. melon (cucumis melo), which having improved humectant property and is capable of giving skin a beautifying effect, improving the color and luster of the skin and exhibiting improved beauty adjusting effect on prevention, improvement in fine wrinkles (Abstract: lines 1-4 and 9-11; page 53, left column, last paragraph).

Hiroaki et al. also teach that the cosmetic composition is obtained by extracting the cucurbitaceous plant with water or water-alcohol solvent, and the amount of the extract obtained

is preferably about 0.001-20 % by weight (Abstract: lines 5-8).

Hiroaki et al. also then teach that the extract is highly safe without giving irritancy to the skin and the cosmetics produce made from such extract is inexpensive because of relatively readily available raw materials (Abstract; lines 9-11).

Finding of prima facie obviousness Rational and Motivation
(MPEP 2142-2143)

It would have been obvious to a person of ordinary skilled in the art at the time the invention was made to combine the teaching of Golz-Berner et al. and Burmeister et al. with Murad, H., Soma et al., Fujimura et al. and Hiroaki et al. to arrive at the instant invention.

One of ordinary skill would have been motivated to combine extracts of pomegranate, fig and musk melon, as well as a ground dry mixture of rosemary, in an anti-aging skin cosmetic composition because the prior art teach the advantages of utilizing the extracts of pomegranate, fig and musk melon, and a ground dry mixture of rosemary for reducing skin fine wrinkle, improved skin texture and color, repair skin elasticity, and repair and rejuvenate UV-damaged skin.

Thus, one of ordinary skill in the art when reading the references set forth above would have been motivated to combine these known ingredients into another known cosmetic composition to form a new skincare composition that can provide the same desirable skin effects as those taught by the prior art, based on their known intention uses in the formulations.

From the teaching of the references, one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention <u>as</u> <u>a whole</u> would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

No claims are allowed.

Contact Information

Any inquiry concerning this communication from the Examiner should direct to Helen Mei-Ping Chui whose telephone number is 571-272-9078. The examiner can normally be reached on Monday-Thursday (7:30 am – 5:00 pm). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where the application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either PRIVATE PAIR or PUBLIC PAIR. Status information for unpublished applications is available through PRIVATE PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the

Application/Control Number: 10/520,562 Page 14

Art Unit: 1616

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free).

/H. C./

Examiner, Art Unit 1616

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616